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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,477

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Charles Y.F. Young

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

4173

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,477	Applicant(s) YOUNG, CHARLES Y.F.	
	Examiner MARCOS SZNAIDMAN	Art Unit 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 3-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4 pages</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1 and 2) in the reply filed on November 30, 2007 is acknowledged.

Status of Claims

Claims 1-40 are currently pending and are the subject of this office action.

Claims 3-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 30, 2007

Claims 1-2 are presently under examination.

Priority

The present application is a 371 of PCT/US04/25336 filed on 08/04/2004, and claims priority to provisional application No. 60/492,367 filed on 08/04/2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1614

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmbrook et. al. (US 2002/0042375) in view of Kim et. al. (American Journal of Pathology, 2002, 160:219-226).

Claim 1 recites a method for monitoring the proliferation of cultured prostate cancer cells in the presence of NSAID, comprising: contacting the prostate cancer cells with one or more NSAID; and determining the level of expression, the transactivation ability, and/or the IL6-mediated activation of an androgen receptor.

Helmbrook et. al. teach a method for treating prostate cancer, which comprises administering to a patient in need thereof at least one non-steroidal anti-inflammatory agent (NSAID) and at least one compound which is a PSA conjugate. (see abstract and page 1, paragraphs [0002] and [0003]). Helmbrook et. al. do not teach determining the level of expression of an androgen receptor. However, Kim et. al teach a quantitative method of determining the level of expression of an androgen receptor in CWR22 human prostate cancer xenograft model using video image analysis, to better understand its role in prostate cancer recurrence after castration (see page 219, first

Art Unit: 1614

column, first sentence; column 2, first sentence of second paragraph, and page 220, column 1, lines 3-8). At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Helmbrook et. al. (contacting the prostate cancer cells with one or more NSAID) and Kim et. al. (determining the level of expression of androgen receptor in prostate cancer cells to better understand its role in prostate cancer recurrence after castration), with the motivation of better monitoring the development of prostate cancer in an individual, thus resulting in the practice of claim 1 with a reasonable expectation of success.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmbrook et. al. (US 2002/0042375) and Kim et. al. (American Journal of Pathology, 2002, 160:219-226) as applied to claim 1 above, and further in view of Nakao et. al. (US 2002/0107273).

Claim 2 recites the same limitations as claim 1, wherein the NSAIDs are celecoxib and/or nimesulide. Helmbrook et. al. and Kim et. al. teach all the limitations of claim 2, except for the specific NSAIDs celecoxib and/or nimesulide. However, Nakao et. al. teach the NSAIDs nimesulide and celecoxib (see page 47, paragraph [0573]). At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Helmbrook et. al. (contacting the prostate cancer cells with one or more NSAID) and Kim et. al. (determining the level of expression of androgen receptor in prostate cancer cells to better understand its role in prostate cancer recurrence after castration) with the teachings of Nakao et. al. (NSAIDs

Art Unit: 1614

nimesulide and celecoxib), with the motivation of monitoring the development of prostate cancer in an individual with well known NSAIDs, thus resulting in the practice of claim 2 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS

January 8, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614